



STATE PROCUREMENT OFFICE
NOTICE OF REQUEST FOR EXEMPTION
FROM HRS CHAPTER 103D

14 DEC -9 A9 32

TO: Chief Procurement Officer

FROM: Health/State Laboratories Division
Name of Requesting Department

ADMINISTRATION
STATE PROCUREMENT OFFICE
STATE OF HAWAII

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods, services or construction:

Primary monkey kidney cells in 16 mm tube format (Rhesus, Cynomolgous, or African Green); and other continuous cell lines including MRC-5 (human embryonic lung fibroblast) in 16 mm tube format, and MDCK (Madin Darby canine kidney) in either flask or tube format. Other cell lines as required.

2. Vendor/Contractor/Service Provider: Diagnostic Hybrids, Inc. is a subsidiary of Quidel Corp.

3. Amount of Request:
\$ 40,000

4. Term of Contract From: 1/2/2015 To: 1/1/2016

5. Prior SPO-007, Procurement Exemption (PE): 14-044B

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

Diagnostic Hybrids, Inc. is the only manufacturer and sole provider of primary monkey kidney cell in 16 mm tube format. Primary monkey cells are isolated from the kidneys of Macaca mulatta (Rhesus), Macaca fascicularis (Cynomolgous), or Cercopithecus aethiops (African Green). The only other known manufacturer and provider of Rhesus primary monkey kidney cell lines and MRC-5 cells in 16 mm tube format was Viomed Laboratories which recently sold their cell culture business to Diagnostic Hybrids, Inc.. (See Attached Letter from Diagnostic Hybrids, Inc.)

Cell lines are susceptible to different viruses. Primary monkey kidney cells, such as from Rhesus or Cynomolgous, are susceptible to enteroviruses, adenoviruses, parainfluenza, and some strains of influenza. MRC-5 are generally susceptible to herpesvirus, cytomegalovirus, and varicella virus. MDCK cells are susceptible to influenza viruses. Virus isolation and propagation is very labor intensive. Primary monkey kidney cells are harvested from the kidneys of various species of monkeys and purchased in either tube format or suspension form. SLD previously purchased the cells in suspension form and propagated (See Attached Sheet)

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:

Diagnostic Hybrids, Inc. is the only known manufacturer and sole provider of primary monkey kidney cells in 16 mm tube format. Other continuous cell lines currently used by the Virology Section include MRC-5 (Human embryonic lung fibroblast) and MDCK (Madin-Darby canine kidney). The continuous cell lines such as MRC-5 and MDCK can be propagated in-house but this laboratory process is very labor intensive and dependent upon the specimen submissions and expected shelf life of the cells in tube format. Since the shelf life and product viability and consistency of the primary kidney cells (Rhesus) and MRC-5 cells upon receipt by our laboratory, Diagnostic Hybrids, Inc. was selected as the manufacturer and provider. Due to the limited shelf life and susceptibility of the MDCK cells, these cell cultures were previously propagated in-house from flasks for a limited number of passages. Due to the current shortage of available analysts, we will also be ordering the MDCK cells in tube format.

8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).

*Point of contact (Place asterisk after name of person to contact for additional information).

| Name | Division/Agency | Phone Number | e-mail address |
|------------------|-----------------|--------------|------------------------------|
| Gail Y. Kunimoto | SLD/MMB | 453-6700 | gail.kunimoto@doh.hawaii.gov |
| | | | |
| | | | |

*All requirements/approvals and internal controls for this expenditure is the responsibility of the department.
I certify that the information provided above is, to the best of my knowledge, true and correct.*

Department Head Signature

12/8/14

Date

For Chief Procurement Officer Use Only

Date Notice Posted: 12/9/14

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is granted for the period 1/2/15 to 1/1/16. This approval is for the solicitation process only, HRS section 103D-310(c) and HAR section 3-122-112, shall apply (i.e. vendor is required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Awards Reporting System.

If there are any questions, please contact Bonnie Kahakui at 587-4702, or bonnie.a.kahakui@hawaii.gov.

☒ Approved

☐ Disapproved

☐ No Action Required

Chief Procurement Officer Signature

12/18/14

Date

6. Explain in detail, why it is not practicable, or not advantageous for the department to procure by competitive means: (continued)

the tubes in-house. Since monkey kidney cells in suspension format are no longer available for purchase and only the 16 mm tube format is available for use for viral isolation in our laboratory, it is not practicable nor advantageous for the Department to procure the primary monkey kidney cells through competitive means because Viomed Laboratories, Inc. (LabCorp) has sold their cell culture business to Diagnostic Hybrids, Inc..

The quantity of cell culture host systems required for virus isolation is determined by the number of specimen submissions which usually average 10,000 specimens per year with a high of 29,000 specimens received during the influenza pandemic of 2009. It is more practicable and advantageous for our laboratory to purchase the primary monkey kidney cells and MRC-5 cells in 16 mm tube format. Cells are routinely received every other week and are increased to weekly shipments during influenza season due to the increase of respiratory specimens. The quantities of cell culture host systems are adjusted as needed depending on the number of specimen submissions.

The manufacturer performs quality control on each lot of their cell culture products and our laboratory performs additional sterility and tests the cell cultures with various virus panels for susceptibility upon receipt.

PE15-0260